Application for Use through 10/31/99. OMB 0651-0031

Applicated for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitu	ute for form 1449A/PTO		Complete if Known			
			Application Number			
	ORMATION D		Filing Date	22798		
STA	ATEMENT BY	APPLICANT	First Named Inventor	BLUME, Richard S.		
		•	Group Art Unit			
	(use as many sheets	as necessary)	Examiner Name			
Shoot			Attorney Docket Number			

TITLE: METHOD AND TEST KIT FOR ORAL SAMPLING É **U.S. PATENT DOCUMENTS** Pages, Columns, Lines U.S. Patent Document Date of Publication of Name of Patentee or Applicant Examine Cite Where Relevant Kind Code Cited Document Passages or Relevant of Cited Document initials' No.1 Number MM-DD-YYYY Figures Appear 4,114,605 McGhee et al. 09-19-1978 4,321,251 Mashberg 03-23-1982 4,397,944 Komura 08-09-1983 4,418,702 Brown et al. 12-06-1983 5,022,409 Goldstein et al. 06-11-1991 5,103,386 Goldstein et al. 04-07-1992 5,339,829 Thieme et al. 08-23-1994 5,479,937 Thieme et al. 01-02-1996 5,563,073 Titmas, T. 10-08-1996 5,573,009 Thieme et al. 11-12-1996

				FORE	GN PATENT DOCUMENTS	S		
Examiner	miner Cite	F	oreign Patent Do		Name of Patentee or	Date of Publication of	Pages, Columns, Lines, Where Relevant	
Initials*	No.1	Office ³	Number ⁴	Kind Code ⁵ (<i>if known</i>)	Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	T⁰
								-
								+
								I
					· · · · · · · · · · · · · · · · · · ·			+
			··· - · · ·					T

	Δ	
Examiner Signature	W/wwd	Date Considered 8//2/999

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Sheet

PTO/SB/08B (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitu	ute for form 1449B/PTC)		Complete if Known			
		_		Application Number	09/031,578		
INF	ORMATION	D	ISCLOSURE	Filing Date 2/17/98			
STATEMENT BY APPLICANT				First Named Inventor	BLUME, Richard S.		
•		•		Group Art Unit			
	(use as many si	heets	s as necessary)	Examiner Name			
heet	2	of	4	Attorney Docket Number			

	TITUS: mechan	1 to pit for our sounding &
	Cite No.1 OTHER PRIOR ART NON PATENT LITERATUR Include name of the author (in CAPITAL LETTERS), title of the article item (book, magazine, journal, serial, symposium, catalog, etc.), date, pp publisher, city and/or country where publisher.	(when appropriate), title of the age(s), volume-issue number(s),
Ph	SINGH, S. et al., "Determinants of esophageal 'alkaline' pH e patients with gastroesophageal reflux disease," <u>Gut</u> , 1993 Ma	
1	CHEN, M., et al., "Gastroesophageal reflux disease: correlation radiographic findings," Radiology, 1992; 185: 483-6	on of esophageal pH testing and
	KAHRILAS, P., "Gastroesophageal reflux disease," <u>IAMA</u> , 19	996 Sep. 25; 276(12): 983-8
	SCHOEMAN et al., "Mechanisms of gastroesophageal reflux subjects," <u>Gastroenterology</u> , 1995 Jan.; 108(1): 83-91	in ambulant healthy human
	RICHTER, J., "Extraesophageal presentations of gastroesoph Gastrointest, Dis., 1997 Apr.; 8(2): 75-89	ageal reflux disease," <u>Semin.</u>
	Wall Street Journal, "When your heartburn starts to linger af 1997	ter the holidays," December 29,
	WIENER, G., et al., "Chronic hoarseness secondary to gastrodocumentation with 24-hour ambulatory pH monitoring," A 1503-8	
	CONTENCIN, P., and NARCY, P., "Gastroesophageal reflux pharyngeal pH monitoring study," <u>Arch. Otolaryngol. Head</u>	
	POPE, C., "Acid-reflux disorders," N. Engl. J. Med., 1994 Sep	8; 331(10): 656-60
	MEURMAN, J., et al., "Oral and dental manifestations in gas Oral Surg. Oral Med. Oral Pathol., 1994 Nov.; 78(5): 583-9	stroesophageal reflux disease,"
m	SCHROEDER, P., et al., "Dental erosion and acid reflux disea Jun. 1; 122(11): 809-15	ase," <u>Ann. Intern. Med.</u> , 1995

			 The state of the s		
Examiner		1/1/1000	Date	Ø /	12/50
Signature	Munel	1 1 W 1 108W	Considered	0/	12/17

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (10-96)
Appload for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitu	ite for form 1449B/PTC	,		Complete if Known			
				Application Number	109/031,578	٦	
INFORMATION DISCLOSURE				Filing Date	427/98	Π	
STA	TEMENT E	BY	APPLICANT	First Named Inventor	BLUME, Richard S.		
	_	-		Group Art Unit			
	(use as many s	heets	as necessary)	Examiner Name			
heet		of		Attorney Docket Number			

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No.1 publisher, city and/or country where published. MADINIER, I., et al., "Oral carriage of Helicobacter pylori: a review," I. Periodontol., 1997 Jan.; 68(1):2-6 SCHINDLBECK, N., et al., "Which pH threshold is best in esophageal pH monitoring?" Am. I. Gastroenterol., 1991; 86(9): 1138-41 ORR, W., et al., "The pattern of nocturnal and diurnal esophageal acid exposure in the pathogenesis of erosive mucosal damage," <u>Am. J. Gastroenterol.</u>, 1994 Apr.; 89(4): 509-12 JACOB, P., et al., "Proximal esophageal pH-metry in patients with reflux laryngitis," Gastroenterology, 1991; 100: 305-10 SHAKER, R., et al., "Esophagopharyngeal distribution of refluxed gastric acid in patients with reflux laryngitis," Gastroenterology, 1995; 109: 1575-82 VAEZI, M., and RICHTER, J., "Twenty-four hour ambulatory esophageal pH monitoring in the diagnosis of acid reflux-related chronic cough," South Med. I., 1997 Mar.; 90(3): 305-11 KOUFMAN, J., and CUMMINS, M., "The prevalence and spectrum of reflux in laryngology: a prospective study of 132 consecutive patients with laryngeal and voice disorders," Center for Voice Disorders of Wake Forest University, 1997 LOCKE III, G., et al., "Prevalence and clinical spectrum of gastroesophageal reflux: A population-based study in Olmsted County, Minnesota," Gastroenterology, 1997; 112: 1448-56 ISOLAURI, J., et al., "Natural course of gastroesophageal reflux disease: 17-22 year follow-up of 60 patients," Am. I. Gastroenterol., 1997 Jan.; 92(1): 37-41 OLDEN, K., and TRIADAFILOPOULOS, G., "Failure of initial 24-hour esophageal pH monitoring to predict refractoriness and intractability of reflux esophagitis," Am. I. Gastroenterol., 1991; 86(9): 1142-6 JAMIESON, J., et al., "Ambulatory 24-hour esophageal pH monitoring: normal values, optimal thresholds, specificity, sensitivity, and reproducibility," Am. I. Gastroenterol., 1992; 87(9): 1102-1110

ire	farily a moord	Date Considere	ared $8/2$	199	
	aun a I morning	Cor	nside	soldorod (A)	soldered M/W/99

^{*}EXAMINER: Initial if réference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Please	type a	nlus	sion :	(ب	inside	this box	
ribaso	type a	pius	Sign	(+)	1115100	II IIS DOX	

PTO/SB/08B (10-96)
Applo-od for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitu	ute for form 1449B/PT	0			Complete If Known			
				201 001177	Application Number	09/03/578		
INF	ORMATION	<i>I</i>		SCLOSURE	Filing Date	2/27/92		
STA	TEMENT B	B \		APPLICANT	First Named Inventor	BLUME, Richard S.		
			_		Group Art Unit			
	(use as many s	she	ets	as necessary)	Examiner Name			
Sheet	4	7	of	4	Attorney Docket Number			

		TITLE: Well and test kit for mil Samplin & Diagn	ni							
	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS 0									
Examiner Cite No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²							
		TEW, S., et al., "The illness behavior of patients with gastroesophageal reflux disease with and without endoscopic esophagitis," <u>Dis. Esophagus.</u> , 1997 Jan.; 10(1): 9-15								
		BARDHAN, K., "Is there any acid peptic disease that is refractory to proton pump inhibitors?" Aliment. Pharmacol. Ther., 1993; 7 Suppl 1: 13-24								
		SACHS, G., "Proton pump inhibitors and acid-related diseases," <u>Pharmacotherapy</u> , 1997 Jan-Feb.; 17(1): 22-37								
		SONTAG, S., et al., "Lansoprazole heals erosive reflux esophagitis resistant to histamine H2-receptor antagonist therapy," <u>Am. J. Gastroenterol.</u> , 1997 Mar.; 92(3): 429-37								
		SHAW, G., et al., "Subjective, laryngoscopic, and acoustic measurements of laryngeal reflux before and after treatment with omeprazole," <u>I. Voice</u> , 1996 Dec.; 10(4): 410-8								
		DEVAULT, K. and CASTELL, D., "Guidelines for the diagnosis and treatment of gastroesophageal reflux disease," <u>Arch. Intern. Med.</u> , 1995; 155(20): 2165-2173								
		HAASE, G., et al., "A unique teletransmission system for extended four-channel esophageal pH monitoring in infants and children," <u>I. Ped. Surg.</u> , 1987 Jan.; 22(1): 68-74								
		CONTENCIN, P., et al., "Measurement of pH of the rhinopharynx in children with gastroesophageal reflux," <u>Presse Medicale</u> , 1989; 18(1): 13-6								
		JOSHI, G., et al., "Continuous hypopharyngeal pH measurement in spontaneously breathing anesthetized outpatients: laryngeal mask airway versus tracheal intubation," Anesth. Analg. , 1996; 82: 254-7								
		AYRE, J., "The gargle test: new oral cancer screening method," NY State Dent. J., 1972 Jun-Jul.; 38(6): 345-50								
pu		LOUGHLIN, C., and and KOUFMAN, J., "Paroxysmal laryngospasm secondary to gastroesophageal reflux," <u>Laryngoscope</u> , 1996, Dec.; 106(12 Pt. 1):1502-1505								

Examiner Signature	Homelale igned	Date S/12/99
		· · · · · · · · · · · · · · · · · · ·

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.